IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STEPHEN WENDELL & LISA WENDELL, as successors in interest to MAXX WENDELL deceased,

Plaintiffs,

v.

JOHNSON & JOHNSON, et al.,

Defendants.

Case No. 09-4124 CW (JSC)

ORDER REGARDING PARTIES' JOINT MEMORANDUM OF LAW ON PLAINTIFFS' MOTION TO COMPEL DISCOVERY (Dkt. No. 280)

Presently before the Court are the following two discovery disputes: (1) whether Defendant Teva Pharmaceuticals USA, Inc. ("Teva") must produce documents and a Rule 30(b)(6) witness concerning Teva's pharmacovigilance beyond 2004, and (2) whether Teva and Par Pharmaceuticals, Inc. ("Par") must respond to Plaintiffs' request for admissions. The Court held a hearing on the parties' disputes on March 7, 2013, and the parties subsequently filed a joint memorandum of law on Plaintiffs' motion to compel discovery. For the reasons stated below, the Court finds that Teva must produce the requested discovery regarding pharmacovigilance beyond 2004. The Court further finds that Teva and Par are not required to respond to the request for admissions because they are untimely.

DISCUSSION

Under the Federal Rules of Civil Procedure a party "may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense. . . . Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." *See* Fed. R. Civ. P. 26(b)(1). The Court has broad discretion to determine relevancy for discovery purposes. *See Surfvivor Media, Inc. v. Survivor Prods.*, 406 F.3d 625, 635 (9th Cir. 2005).

I. Plaintiffs' Request for Production

Plaintiffs move to compel responses to Plaintiffs' First Requests for Production of Documents, No. 9, which requests:

> Any and all Post Market reporting and/or Post Marketing Surveillance documents and materials including all Medwatch forms, all Adverse Drug Experience (ADE) reports, including, but not limited to, any and all corresponding documents, materials, notes, written and underlying data, including electronic data, correspondence, follow up communications, investigations and memoranda relating to every and all adverse experiences and/or events concerning the ingestion and use of 6-MP, and/or its chemical bioequivalent, reported to and/or known by Defendant or of which Defendant was or is otherwise aware.

(Dkt. No. 280-3 at 3-4.) Teva asserts that it will produce documents, and provide a Rule 30(b)(6) witness to testify regarding those documents, only for the period between July 1, 2003 to July 2004, when Maxx Wendell took his last dose of Teva's brand-name product and began taking Par's generic version. Teva contends that since this is a products liability action, its liability ends once Maxx ceased using its product; thus, any discovery into its actions after July 2004 is irrelevant. Plaintiffs argue that Teva should be compelled to produce the requested discovery covering the time period from July 1, 2003 to July 2007, when Maxx was diagnosed with hepatosplenic T-cell lymphoma ("HSTCL"). Plaintiffs reason that they need this discovery in the event the District Court decides in their favor regarding the scope of Teva's liability—that is, if the District Court finds that Teva can be liable for its negligence in failing to warn of the drug's harmful effects even though Maxx was no longer using Teva's product. The Court agrees with Plaintiffs.

As an initial matter, the Court notes that Teva does not contend that there is any burden in producing the requested discovery. In fact, at the hearing, Teva asserted that, at least as to the adverse events reports, it would not be burdensome to produce them. (Dkt. No. 279 at 15:19-21 ("[T]hose are the kinds of things that they -- that wouldn't be -- they wouldn't want to do it, they wouldn't be happy about it, but they could do it.").) Teva's challenge to Plaintiffs' discovery requests relate solely to relevance. Rule 26(b)(2) instructs courts that discovery may be limited if a court determines that "*the burden or expense of the proposed discovery outweighs its likely benefit*, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery involving the issues." Fed R. Civ. P. 26(b)(2)(C)(iii) (emphasis added). Given that Teva has not identified any burden in producing the requested discovery, Plaintiffs' burden in demonstrating that the requested discovery is relevant and likely beneficial is accordingly low.

Plaintiffs base their relevance argument regarding Teva's post-2004 liability primarily on *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008). The plaintiff in *Conte* brought claims for fraud, fraud by concealment, and negligent misrepresentation against drug company Wyeth. 168 Cal. App. 4th at 95. Wyeth argued, among other things, that the plaintiff's negligent misrepresentation claim regarding the warning on Wyeth's drug failed because it was undisputed that the plaintiff did not consume its brand-name drug; rather, the plaintiff consumed the generic version and "Wyeth has no duty to users of the generic version of its products, which are produced by other manufacturers." *Id.* at 100-01. The court disagreed with Wyeth, finding on an issue of first impression that the plaintiff stated a claim for negligent misrepresentation against Wyeth. *See id.* at 102-11. Specifically, the court found that "a name-brand prescription drug manufacturer in disseminating product warnings owes a duty of care to patients who take a generic version of the drug pursuant to a prescription written in reliance on the name-brand maker's information." *Id.* at 103.

In reaching this conclusion regarding duty, the court examined the foreseeability of harm associated with Wyeth's conduct and weighed the various policy factors implicated by recognizing Wyeth's duty. Regarding foreseeability, the court specifically addressed the issue in the context of misrepresentation torts, where "duty and reasonable reliance are closely connected." *Id.* at 104

(internal quotation marks omitted). After examining other California cases where a duty of care was found based on the foreseeability of reliance on the misrepresentation, the court "h[ad] no difficulty concluding that Wyeth should reasonably perceive that there could be injurious reliance on its product information by a patient taking generic metoclopramide." *Id.* at 105. The court reasoned as follows:

> In California, as in most states, pharmacists have long been authorized by statute to fill prescriptions for name-brand drugs with their generic equivalents unless the prescribing physician expressly forbids such a substitution. It is therefore highly likely that a prescription for Reglan written in reliance on Wyeth's product information will be filled with generic metoclopramide. And, because by law the generic and name-brand versions of drugs are biologically equivalent, it is also eminently foreseeable that a physician might prescribe generic metoclopramide in reliance on Wyeth's representations about [the name-brand product].

Id. (internal citations omitted). The court further held that Wyeth failed to identify policy considerations that would override the foreseeability of risk. *Id.* at 107.

Plaintiffs argue that *Conte*'s holding regarding the duty of due care applies to their case with equal force, notwithstanding that Plaintiffs' claim is for ordinary negligence and not negligent misrepresentation. The parties have not yet presented this legal issue to the District Court. Plaintiffs argue that the *Conte* court excluded from its holding only those product liability claims based on a strict liability theory; those based on negligent failure to warn come within its holding. However, Defendants correctly observe that other language in the opinion suggests that *all* product liability claims, whether under strict liability or negligence, fall outside the court's holding. *Compare Conte*, 168 Cal. App. 4th at 101 (rejecting defendant's argument that it can't be liable for third-party's product, reasoning that "[t]he conclusion would be sound were Conte in fact pursuing a cause of action against Wyeth for strict products liability. But she is not") *and* ("Negligence and strict products liability are separate and distinct bases for liability that do not automatically collapse into each other because the plaintiff might allege both when a product warning contributes to her injury.") *with id.* at 102 ("[T]he trial court was correct in its assumption that 'this is a case involving legal principles of negligent misrepresentation, and not a products liability action.'") *and id.* at 111 ("Here . . . the trial court misapplied to Ms. Conte's fraud and negligent misrepresentation claims the rule that no *products liability* exists unless the defendant manufactured or sold the injurious product that causes

injury.") (emphasis original). Given that the *Conte* court's duty holding was rooted in the specific context of misrepresentation torts, the Court is not persuaded that *Conte*'s holding plainly covers Plaintiffs' negligence claim.

The Court also declines to find, as urged by Plaintiffs, that the Ninth Circuit has interpreted *Conte* to cover all negligence claims. In *Rosa v. Taser Intern., Inc.*, 684 F.3d 941, 949 (9th Cir. 2012), the court gave *Conte* an abbreviated review, summarizing the holding of the case as follows: "when the user of a generic pharmaceutical sues the manufacturer of the brand name medication for the warning included in the Physician's Desk Reference, the user cannot recover under strict liability because he or she was not injured by the manufacturer's own products. However, because the brand name manufacturers are responsible for disseminating the information in the Physician's Desk Reference, which others would foreseeably rely upon, they may be held liable under negligence." (citations omitted). Although the court's interpretation of *Conte* matches Plaintiffs', the court's lack of explanation in how it reached its interpretation is unhelpful in resolving the apparent ambiguity in the *Conte* decision. Further, the court's description of *Conte* was in dicta as it ultimately held that *Conte* did not apply the facts of the case before it. *Id.* ("Such a duty thus arises only in narrow circumstances that are not present here."). It does not follow, however, that because *Rosa* is not as strong as urged by Plaintiffs, or that *Conte* is not on all fours with this case, that Plaintiffs will be unsuccessful in extending *Conte*'s holding to cover negligence claims beyond negligent misrepresentation claims. Teva has cited no case, and the Court finds none, that has rejected Plaintiffs' argument.

To be sure, courts, including the California Supreme Court, have rejected arguments similar to Plaintiffs', but under different circumstances from here. For instance, in *O'Neil v. Crane Co.*, 53 Cal. 4th 335, 342-43 (2012), the court held that a manufacturer of pumps and valves used in Navy warships was not liable in strict liability or negligence for the plaintiffs' asbestos exposure because the products that released the asbestos—external insulation and internal gaskets and packing used in conjunction with the manufacturer's pumps and valves post-sale—were made by a third party. Regarding the manufacturer's duty of care, the court assumed that foreseeability of harm existed, but found that "strong policy considerations counsel against imposing a duty of care on pump and valve

manufacturers to prevent asbestos-related disease." *Id.* at 364-65. The court's analysis of the policy considerations was specific to the manufacturer and its relation to the third-party manufacturer: "Nor would imposing a duty of care in this context be likely to prevent future harm. There is no reason to think a product manufacturer will be able to exert any control over the safety of replacement parts or companion products made by other companies." *Id.* at 365. As the *Conte* court recognized, however, the relationship between brand-name and generic drug manufacturers reveals that the brand-name drug manufacturer *does* exert a level of control over the labeling of the generic drugs. Indeed, the United States Supreme Court recently deferred to the Federal Drug Administration's interpretation of its regulation that "that the warning labels of a brand-name drug and its generic copy must always be the same." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574-75 (2011) (citing 57 Fed. Reg. 17961 (1992) ("[T]he [generic drug's] labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for [generic drug] approval.")). Although *O'Neil* favors Teva in the sense that it affirms the general protection of manufacturers from liability for harm caused by a third party's product, the *O'Neil* court's holding rests on the particular circumstances in that case, which did not warrant extending the duty of due care. Plaintiffs here have at least a reasonable argument that this case, unlike *O'Neil*, warrants an extension of the duty of due care given the brand-name manufacturer's control over labeling.

The issue, however, is for the District Court to resolve once the parties submit the matter to it for decision. It is enough to find for purposes of the present discovery dispute that the likely benefit of the requested discovery is not outweighed by the burden on Teva in producing it. This conclusion also makes sense from a case management perspective. If the District Court rules in Plaintiffs' favor on the duty of care issue, the case management schedule could be delayed due to the need to conduct Plaintiffs' requested discovery if that discovery is not conducted now. Given that Teva has identified no undue burden in producing the requested discovery, the Court will order such discovery to occur now rather than risk reopening discovery somewhere down the road, closer to trial.

II. Plaintiffs' Request for Admissions

Plaintiffs served their request for admissions ("RFAs") on Teva and Par on February 26, 2013—the day of the discovery cut-off. In this District, "a 'discovery cut-off' is the date by which all

responses to written discovery are due and by which all depositions must be concluded." Civ. L.R. 37-3 (emphasis added). Because Teva's and Par's responses to the RFAs were not due until after the discovery cut-off, the Court denies Plaintiffs' request to compel their responses to the RFAs.

The Court rejects Plaintiffs' argument that their RFAs should not denied as untimely because RFAs are not discovery and therefore not subject to the discovery cut-off. Plaintiffs' cited authorities do not support such a proposition; rather, they simply stand for the undisputed assertion that RFAs should be used to "establish admission of facts about which there is no real dispute," not "to elicit facts and information and to obtain production of documents." 7-36 MOORE'S FEDERAL PRACTICE—CIVIL § 36.02 (2013). While RFAs "are distinguishable from *other* discovery devices," they are still a discovery device. *Id.* (emphasis added); *see also* Charles Alan Wright, Arthur R. Miller, and Richard L. Marcus, 8B FEDERAL PRACTICE & PROCEDURE § 2252 (3d ed. 2010) ("Wright & Miller") ("Rule 36 [governing RFAs] has not been resorted to as much as some of the *other* discovery rules . . . .") (emphasis added); *but see* Wright & Miller § 2253 ("Strictly speaking Rule 36 is not a discovery procedure at all, since it presupposes that the party proceeding under it knows the facts or has the document and merely wishes its opponent to concede their genuineness."). In addition, the District's Local Rules treat RFAs as discovery. *See* Civ. L.R. 26 (entitled "General Provisions Governing Discovery" and providing that "[t]he party propounding interrogatories, requests for production of documents, or *requests for admission* must retain the original of the discovery request and the original response.") (emphasis added).

The Court also rejects Plaintiffs' assertion that the issue is moot because Teva and Par responded to the RFAs. Defendants' response to the RFAs is expressly conditioned on this Court's determination that they are required to respond to the RFAs. (*See* Dkt. No. 280-3.) The issue is not moot because Defendants' response is effective only if the Court rules in Plaintiffs' favor. The Court has not and therefore Defendants' responses to the RFAs should be deemed stricken.

CONCLUSION

For the reasons stated above, the Court GRANTS in part and DENIES in part Plaintiffs' motion to compel. Teva shall produce documents pursuant to Plaintiffs' First Request for Production of Documents, No. 9, covering the time period from July 1, 2003 to when Maxx was diagnosed with

HSTCL in July 2007. Teva shall also produce a Rule 30(b)(6) witness to testify on the topic of pharmacovigilance covered by Request for Production of Documents, No. 9. This discovery shall be completed no later than May 13, 2013. Plaintiffs' request to compel Defendants' responses to their RFAs is denied and Defendants' conditional response to the RFAs is stricken.

IT IS SO ORDERED.

Dated: April 22, 2013

JACQUELINE SCOTT CORLEY
UNITED STATES MAGISTRATE JUDGE

United States District Court
Northern District of California